UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge **Oral Argument Requested**

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO PARTIALLY EXCLUDE OPINIONS OF DR. RAMIN NAJAFI

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INTRODUCTION

Plaintiffs' opposition fails to refute defendants' three primary arguments as to why Dr. Najafi's opinions are inadmissible.

First, Dr. Najafi lacks scientific support for his opinion that defendants "should have been able to predict that nitrosamines could form" during certain processes used by ZHP to manufacture its valsartan active product ingredient ("API"). (Opp'n at 7.) While plaintiffs highlight a few isolated references to nitrosamines in a textbook and some articles, they come nowhere close to showing that chemists could or should have known that nitrosamines could form in the manufacturing conditions used by ZHP. Indeed, Dr. Najafi admitted that he did not know about the potential NDEA reaction until he was retained to serve as an expert.

Second, Dr. Najafi did not disclose an opinion in his report that ZHP should have suspected the raw materials used in its manufacturing processes were contaminated at the time of purchase. And in any event, plaintiffs still have not brought forward any evidence to show that such contamination occurred, rendering such an opinion irrelevant even if it had been timely disclosed.

Third, plaintiffs contend that Dr. Najafi's work as a chemist qualifies him to opine on the meaning of FDA regulations and the carcinogenicity of nitrosamines, but both contentions are contrary to the record and to applicable law.

For all of these reasons, defendants' motion should be granted.

ARGUMENT

I. DR. NAJAFI LACKS A RELIABLE BASIS TO OPINE THAT DEFENDANTS SHOULD HAVE ANTICIPATED THE FORMATION OF NDMA OR NDEA.

As explained in defendants' opening brief, Dr. Najafi lacks a reliable basis to opine that ZHP or any other defendant should have anticipated the formation of NDMA or NDEA during the Zinc Chloride and TEA with quenching processes, respectively. (Mem. at 12-17.) Plaintiffs' arguments to the contrary are meritless.

First, plaintiffs are incorrect that Dr. Najafi can rely solely on his "general experience" and "scientific knowledge of chemicals and universal chemical reaction principles" to opine that defendants should have recognized the risk of nitrosamine formation in ZHP's manufacturing processes. (*See* Opp'n at 8.) The relevant caselaw, which plaintiffs make no effort to distinguish or address, makes clear that opinions about what was or should have been known in a particular field at a given time must be based on authoritative literature, "such as a survey or a widely distributed publication," to be admissible. *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, No. 19md2885, 2021 WL 684183, at *4 (N.D. Fla. Feb. 11, 2021) ("*In re Earplugs*"). (*See also* Mem. at 12 (citing *Grimes v. Hoffmann-LaRoche, Inc.*, 907 F. Supp. 33, 37-38 (D.N.H. 1995)); *id.* at 13 n.5 (collecting cases).) Plaintiffs' lone authority, *Westley v. Ecolab, Inc.*, No. 03-CV-1372, 2004 WL 1068805 (E.D. Pa. May 12, 2004), is not to the contrary. There, the experts at issue sought to opine

about whether the defendant's products caused the plaintiff's injuries, not about what was known in a scientific field. *See, e.g., id.* at *3 ("Plaintiff seeks to offer the testimony of Dr. Michael J. Coyer who will testify as to the cause of [p]laintiff's injuries."). The *Westley* court never suggested that opinions about what was known or should have been known in the scientific community were admissible without authoritative scientific support.

Second, Dr. Najafi has not identified authoritative literature supporting his opinion that a "reasonable chemist" would have expected that the dimethylamine ("DMA") and diethylamine ("DEA") necessary to produce NDMA and NDEA, respectively, could form during the Zinc Chloride and TEA with quenching processes.[1] While plaintiffs suggest that the use of sodium nitrite should have put defendants on notice that nitrosamine formation was possible (*see* Opp'n at 7-10), Dr. Najafi admits that "[t]o form NDMA, you need dimethylamine [and] [t]o form NDEA, you need diethylamine" (1/18/23 Najafi Dep. 193:21-22 (ECF 2292-4)). Dr. Najafi has not pointed to any evidence that ZHP chemists should have suspected –

[1] Contrary to plaintiffs' assertion, defendants' argument is not that Dr. Najafi failed to identify "a published article showing that the exact chemicals used in the ZHP manufacturing processes combined in the exact same way under the exact same conditions combined to form NDMA or NDEA." (Opp'n at 6.) Rather, Dr. Najafi failed to present evidence from which one could extrapolate that the chemistry community had knowledge of the risk of nitrosamine formation in conditions like those present in ZHP's reactions. For that reason, his opinions are inadmissible. *See In re Earplugs*, 2021 WL 684183, at *4.

or would have concluded based on a review of the literature if they had suspected – that either DMA or DEA would be part of the valsartan API manufacturing process.

With respect to the Zinc Chloride process, plaintiffs do not dispute that Dr. Najafi relies solely upon *Purification of Laboratory Chemicals*, Armarego, WLF (4th Edition 1996; 6th Edition 2009) ("Armarego"), for his opinion that reasonable chemists should have expected that DMF could degrade into DMA. Nor do they dispute that the temperature at which Armarego states that DMF will degrade is ***significantly higher*** than the temperature present in the Zinc Chloride process. Instead, plaintiffs argue that "it is a basic chemistry principle that if a chemical degrades at a high temperature, over time it will degrade at a lower temperature as well." (Opp'n at 11 (citing 1/18/23 Najafi Dep. 208:6-11, 208:16-19).) But Dr. Najafi, who did not offer this opinion or provide any support for it in his report, essentially admitted at his deposition that it was based on his own ipse dixit, not reliable science. (*See* 1/18/23 Najafi Dep. 208:12-17 ("**Q.** [D]o you have any citation that would support the notion that DMF at the temperature in which the zinc chloride process was run degrades? **A.** I don't have any citations offhand, but you can take my word to [the] bank.").) *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (approving the exclusion of evidence "that is connected to existing data only by the *ipse dixit* of the expert"). Similarly, while plaintiffs point to Armarego's statement that DMF's decomposition can be catalyzed by acidic materials (Opp'n at

11), the room temperature example it provides involved extremely strong solid bases, not sodium nitrite, *see* Armarego at 192 ("[D]ecomposition is catalysed by acidic or basic materials, so that even at room temperature DMF is appreciably decomposed if allowed to stand for several hours with solid KOH, NaOH or CaH_2.").[2] Notably, Dr. Najafi admitted that he could not provide any estimate of the degree of degradation of DMF that would have occurred at the temperature and conditions in the Zinc Chloride process. (*See* 1/18/23 Najafi Dep. 212:21-25 ("**Q.** But you can't say with any certainty what degree of degradation there may have been of DMF at the temperature and conditions in the zinc chloride process? **A.** I cannot tell[.]").)[3] In short, Armarego could not have put reasonable chemists on notice that DMA could form in the Zinc Chloride process.

As to the TEA with quenching process, plaintiffs contend that a single article identified by Dr. Najafi for the first time at his deposition supports his opinion that

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[2] As defense expert Dr. Fengtian Xue explained and as every chemist knows, KOH, NaOH and CaH_2 are all powerful *bases*, not acids. (*See* Report of Fengtian Xue, Ph.D. at 17, Dec. 22, 2022 (ECF 2288-2, Ex. 2).)

[3] Plaintiffs' reliance on the testimony of Dr. Eric Gu, President of Shanghai SynCores, which was not cited or considered by Dr. Najafi, is also unhelpful. Dr. Gu merely agreed that it was known that DMF could degrade under "certain circumstances," not that DMF would degrade under the conditions present in the Zinc Chloride process. (*See* Dep. of Eric Gu, Ph.D. 183:15-21, Apr. 5, 2021 (Opp'n Ex. M) (ECF 2328-2) ("**Q.** It was known in the chemistry community that DMF could decompose to yield dimethylamine under certain circumstances. That's a correct statement, correct? **A.** Under certain circumstances, yes.").)

defendants should have known that triethylamine ("TEA") would react with sodium nitrite to create the DEA necessary for the formation of NDEA. (Opp'n at 9 (citing 1/24/23 Najafi Dep. 285:17-286:9 (ECF 2292-12) (discussing Loeppky (1984))).) But as explained in defendants' opening brief, Loeppky (1984) observed that certain N-nitrosamines were formed when certain secondary and tertiary amines were heated with sodium nitrite in the presence of diacetyl glycol (also called ethylene glycol diacetate) in an ethylene glycol solution, which was critical to the reaction. (Opp'n at 8-9 (citing Loeppky (1984)).) While plaintiffs assert that ZHP's TEA with quenching process also involved these substances (*id.* at 9), Dr. Najafi admitted at his deposition that this is not the case (*see* 1/24/23 Najafi Dep. 285:14-17 ("**Q.** I was asking if ZHP's zinc chloride or TEA with quenching manufacturing processes involved the use of ethylene glycol as a solvent? **A.** No, it does not use ethylene glycol."); *id.* 287:20-25 (confirming the absence of 2-acetoxylethanol)).

Moreover, plaintiffs cannot dispute that Dr. Najafi's opinion that reasonable chemists should have suspected in 2011 that TEA could degrade into DEA and react with sodium nitrite to form NDEA is belied by Dr. Najafi's testimony that even he was unaware of this reaction until ***after*** he was retained and started researching how NDEA could have formed during the TEA with quenching process, forearmed with the knowledge that it had in fact formed. (1/18/23 Najafi Dep. 193:8-24.) While plaintiffs focus on Dr. Najafi's testimony that he has allegedly known amines could

react with sodium nitrite to form nitrosamines for decades (Opp'n at 10 (citing 1/18/23 Najafi Dep. 114:1-14)), Dr. Najafi lacks any objective basis to assert that it was common knowledge among chemists that TEA could be converted into DEA.

Third, plaintiffs cite various company documents, company witness testimony and post-recall FDA statements as supposed evidence that defendants should have expected the presence of DMA and DEA in the manufacturing process. (*See, e.g.*, Opp'n at 15; Opp'n Ex. P (ECF 2328-2).) But materials documenting ZHP's investigation of the possible sources of NDMA and NDEA in valsartan ***after*** the nitrosamines were discovered are irrelevant to determining whether a reasonable chemist would have recognized the risk of nitrosamine formation ***while the manufacturing processes at issue were being developed and used***, based on the science available at that time. (*See* ECF No. 2322, at 24-25.)[4]

In short, plaintiffs' opposition fails to show that Dr. Najafi had an objective and reliable basis for opining that a reasonable chemist would have recognized a risk of nitrosamine formation in ZHP's valsartan manufacturing process prior to 2018.

[4] Likewise, Dr. Jinsheng Lin's email of July 27, 2017, ***does not*** show that ZHP was aware of the risk of nitrosamine formation in its valsartan manufacturing processes. (*See* ECF No. 2322, at 27.) And even if it did, Dr. Najafi would still lack a scientific basis to opine that ZHP knew there was a risk of nitrosamine formation based on the scientific literature prior to the date of that email.

See In re Earplugs, 2021 WL 684183, at *4; *Grimes*, 907 F. Supp. at 37-38. Accordingly, this opinion should be excluded.

II. DR. NAJAFI SHOULD BE PRECLUDED FROM TESTIFYING ABOUT THE POSSIBILITY OF CONTAMINATION IN THE RAW MATERIALS USED BY ZHP.

Dr. Najafi should also be barred from testifying that defendants should have suspected that the DMF used in the Zinc Chloride process was contaminated with DMA, or that the TEA used in the TEA with quenching process was contaminated by DEA, because: (1) his report did not disclose or support these opinions; and (2) the opinions do not "fit" the facts of the case.

In attempting to show that the opinions were disclosed, plaintiffs quote portions of Dr. Najafi's report that they claim refer to DMA and DEA as "being present" in DMF and TEA, respectively, but the vast majority of those statements expressly refer to the ***degradation*** of these materials during the manufacturing process, not raw material contamination. (*See, e.g.*, Opp'n at 17 ("DMF solvent has been long known to decompose into dimethylamine.").) Dr. Najafi's stray quotations of post-recall documents referring to DMA and DEA as "impurit[ies]/degradant[s]" (*id.*) are also insufficient to support an opinion about raw material contamination, especially since Dr. Najafi did not cite ***any*** scientific literature or other evidence to this effect in his report. *See Krys v. Aaron*, 112 F. Supp. 3d 181, 207 (D.N.J. 2015) (excluding opinion that expert failed to properly

disclose); *Bowers v. Nat'l Collegiate Athletic Ass'n*, 564 F. Supp. 2d 322, 350 (D.N.J. 2008) (excluding opinion "based on little more than 'subjective belief or unsupported speculation'") (citation omitted); *see also Stein v. Foamex Int'l, Inc.*, No. 00-2356, 2001 WL 936566, at *7 (E.D. Pa. Aug. 15, 2001) (excluding affidavit; expert's "[r]eport and deposition testimony" could not have put the defendants on notice regarding opinions that did not "explicitly" appear in his report).[5]

Plaintiffs' cases are not to the contrary. For example, in *Ouelette v. Coty US, LLC*, the court allowed a defense expert to opine that exposure to wax at "127 degrees Fahrenheit" could not have caused the burns alleged by the plaintiff because this opinion was necessarily covered by the statement in the expert's report "that '[w]hile air or water temperatures of 140°F may be uncomfortable, such temperatures do not create rapid burning of the skin'" and therefore there was no surprise or prejudice to the party opposing the testimony. No. 14-CV-00712, 2016 WL 1650775, at *2 (M.D. Pa. Apr. 25, 2016) (Opp'n at 18). And in *In re Paoli Railroad Yard PCB Litigation*, the U.S. Court of Appeals for the Third Circuit

[5] Plaintiffs make no attempt to distinguish *Bowers*, conceding its relevancy, and their attempt to distinguish *Krys* is misguided. As just explained, Dr. Najafi's report did not explain or analyze whether ZHP should have been testing raw materials. (*See generally* Najafi Rep. (ECF 2292-6).) Rather, the report contained a few stray, unsupported statements on this topic. Thus, just as in *Krys*, Dr. Najafi's report deprived defendants of "adequate notice, and the ability to assess the underpinnings of the opinion in connection with [his] deposition." *Krys*, 112 F. Supp. 3d at 207.

reversed a district court's exclusion of an expert's testimony because the expert had "provided most of the substance of his testimony by the deadline, provided the additional substance shortly after the deadline when requested to do so, and had little to gain from the month delay in provision of the additional material." 35 F.3d 717, 793 (3d Cir. 1994) (Opp'n at 18).

Here, by contrast, Dr. Najafi's opinion that ZHP should have suspected that DMA and DEA was present in raw materials it received from suppliers is ***not*** a logical extension of, and is in fact contrary to, his disclosed opinions that DEA and DMA formed as a result of the degradation of DMF and TEA ***when exposed to sodium nitrite during the quenching step of the manufacturing process***. Moreover, allowing him to offer this testimony would severely prejudice defendants, whose experts did not have the opportunity to address Dr. Najafi's contamination opinions – or the materials that plaintiffs' counsel now claim support them – in their own expert reports.

In any event, the documents cited by plaintiffs are insufficient to establish that DEA and DMA were present in ZHP's raw materials.[6] Despite admitting that ZHP's post-recall testing of its DMF found no DMA (Opp'n at 19-20 & Opp'n Ex. L (ECF 2328-2), plaintiffs ask this Court to speculate ***that there was*** DMA because the test

[6] Plaintiffs' opposition attempts to confuse the issue by including extraneous facts related to Dr. Najafi's ***degradation*** theory. (*See* Opp'n at 19.)

ZHP used could not prove that there was none present. But the mere possibility that a trace amount of DMA could have been present in ZHP's DMF is insufficient to meet plaintiffs' burden to show that it ***was*** present. Thus, Dr. Najafi's untimely theory is also inadmissible because it does not fit the facts of this case.

III. DR. NAJAFI IS NOT QUALIFIED TO OFFER REGULATORY OPINIONS.

Contrary to plaintiffs' assertions (Opp'n at 20-22), Dr. Najafi's various experiences have not given him particularized expertise in pharmaceutical API regulation. And even if they had, he cannot testify as to any defendant's compliance with regulatory standards or requirements.

First, Dr. Najafi worked at each of Aldrich Chemical Company and Rhone Poulenc Rorer for less than 3 years more than 25 years ago. (Najafi Rep. Ex. A at 4 (ECF 2292-6).) While he asserts that he was involved in manufacturing drug candidates – i.e. potential drug substances yet to be approved as APIs – ***pursuant*** to a Good Manufacturing Practice protocol (*see id.*), his CV lacks any indication that he was responsible for ensuring compliance with cGMPs. (*See generally* Najafi. Rep. Ex. A.) Indeed, Dr. Najafi has previously acknowledged that he never "worked in regulatory affairs for any generic manufacturer." (2/3/22 Najafi Dep. 156:13-14 (ECF 2292-5).)

Dr. Najafi also conceded that he "contracted out the procedure and the methodology to manufacture" the investigational drug he developed at NovaBay

Pharmaceuticals to a third party (1/18/23 Najafi Dep. 22:1-4) and that NovaBay Pharmaceuticals never manufactured any pharmaceutical API (*id.* 22:6-8). In sum, Dr. Najafi has never been responsible for developing a manufacturing protocol to ensure that pharmaceutical API is manufactured according to cGMP. Rather, he has simply followed the guidelines others have prepared for him, if at all. For this reason alone, Dr. Najafi's regulatory opinions should be excluded. *See Rheinfrank v. Abbott Lab'ys, Inc.*, 680 F. App'x 369, 376, 381 (6th Cir. 2017).[7]

Second, even if he were qualified to offer them, Dr. Najafi's regulatory opinions would still be inadmissible under Third Circuit law. Plaintiffs' opposition ignores the explanation in *Krys* that, under Third Circuit law, "an opinion on the issue of whether a party complied with and/or violated 'legal duties' constitutes an

[7] Plaintiffs' attempt to distinguish *Rheinfrank* is unpersuasive. Like the *Rheinfrank* experts, Dr. Najafi lacks experience in ensuring compliance with the regulations he seeks to opine that defendants failed to follow; thus, his regulatory opinions should be excluded. By contrast, plaintiffs' cases are inapposite. All the regulatory experts who were ***not excluded*** in *In re Proton-Pump Inhibitor Products Liability Litigation* had experience at the FDA, *see generally* MDL No. 2789, 2022 WL 18999830 (D.N.J. July 5, 2022), which Dr. Najafi does not (1/18/23 Najafi Dep. 19:13-15). Similarly, in *In re Heparin Product Liability Litigation*, the court concluded that the witness's "extensive relevant experience as a research scientist, consultant, and pharmaceutical executive in drug development, manufacturing and ***quality control***" provided him a sufficient basis to opine "about the need to test ingredients and final products to confirm compliance with regulatory standards for purity and safety." MDL No. 1953, 2011 WL 1059660, at *4 (N.D. Ohio Mar. 21, 2011) (emphasis added). Dr. Najafi has no similar quality control experience. (*See generally* Najafi Rep. Ex. A.)

impermissible legal opinion, even if offered by a well-qualified expert." *Krys*, 112 F. Supp. 3d at 193 (citing *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006)). And, contrary to plaintiffs' assertions, Dr. Najafi's opinions do not merely address defendants' underlying conduct; rather, they offer inadmissible legal conclusions that defendants violated regulatory standards. (*See, e.g.*, Najafi Rep. at 38 ("The Valsartan containing products that had NDMA and NDEA were adulterated (21 USC Section 351) . . . .").)[8] Finally, even if some of Dr. Najafi's opinions were admissible under *Berckeley*, the Court has already explained that Dr. Najafi's regulatory opinions wade too far into the domain of the factfinder, and plaintiffs offer nothing but *ipse dixit* in response. (ECF No. 2261, at 91.)

IV. DR. NAJAFI IS NOT QUALIFIED TO OPINE ON THE TOXICITY OF NDEA/NDMA OR GENERAL CAUSATION.

Finally, plaintiffs concede that Dr. Najafi is not qualified to offer general causation opinions, but assert that he should nevertheless be allowed to testify regarding the "genotoxic/carcinogenic nature of these chemicals due to their

[8] Likewise, the caselaw cited by plaintiffs in support of their argument either (1) was decided outside the Third Circuit, *see, e.g.*, *Alto v. Sun Pharm. Indus., Inc.*, No. 19-cv-09758, 2021 WL 4803582 (S.D.N.Y. Oct. 13, 2021); or (2) failed to grapple with *Berckeley*'s holding, *see, e.g.*, *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, No. 13-4663, 2019 WL 4751883 (E.D. Pa. Sept. 30, 2019) (lacking a cite to *Berckeley*); *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 660 (E.D. Pa. 2012) (failing to acknowledge *Berckeley'*s relevant holding). (Opp'n at 23-26.)

chemical structure." (Opp'n at 27-28.) But Dr. Najafi's report does not contain any independent opinion about how the chemical structure of nitrosamines causes cancer or gene damage. Instead, it appears that Dr. Najafi simply intends to opine that NDMA and NDEA "are potent genotoxic, carcinogens and provide zero benefit to the patient," particularly "when patients are taking these drugs on [a] long term or chronic basis." (*See* Najafi Rep. at 38.) Plaintiffs cannot point to any specialized experience or knowledge in medical causation or toxicology on Dr. Najafi's part that would allow him to offer such opinions. (*See* Opp'n at 25-26 (collecting cases precluding experts that lacked toxicological or epidemiological credentials from opining regarding the toxicity of substances).) And to the extent Dr. Najafi seeks to testify that NDMA and NDEA have been recognized by the FDA and other regulatory bodies as "high potency genotoxic carcinogens" (Najafi Rep. at 8 (citing EMA Guideline on the Limits of Genotoxic Impurities, Jan. 2007-Jan. 2018, https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-limits-genotoxic-impurities_en.pdf)), a jury is more than capable of understanding such evidence, and it would be inappropriate to allow Dr. Najafi to simply paraphrase these materials with his own narrative gloss. *See, e.g.*, *Newman ex rel. Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 9936293, at *5 (N.D. Ill. Mar. 29, 2013) (excluding expert where much of her testimony "consist[ed] of quoted portions of the [FDA] regulations themselves or descriptions of what the

regulations require" and created a risk that jurors would "mistakenly conclude that her opinion or conclusion is the law").

CONCLUSION

For the foregoing reasons and those set forth in defendants' opening brief, Dr. Najafi's opinions should be excluded from trial.

Dated: April 25, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 25, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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